IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

DAVID G. JACKSON, and DEBRA F. JACKSON, Plaintiffs, v. PFIZER, INC., WYETH, and WYETH PHARMACEUTICALS, Defendants.	)	8:05CV18 MEMORANDUM AND ORDER

This matter is before the court on defendants' motions for summary judgment, Filing Nos. 39 and 46, and request for hearing, Filing No. 71. Defendants contend that plaintiffs' claims rely on Nebraska common law which has been preempted by the Food and Drug Administration (FDA). Plaintiffs have sued the defendants for strict liability and negligence causes of action. They alleged that the drug Zoloft, manufactured and sold by Pfizer, and the drug Effexor, manufactured and sold by Wyeth and Wyeth Pharmaceuticals, caused their son Jacob Jackson to commit suicide. Plaintiffs contend that the duties under Nebraska common law require additional warnings relating to the risk of suicide. The court has carefully reviewed the record and the relevant case law and concludes the motions should be denied.

Background

The plaintiffs' eleven year old son Jacob suffered from severe depression. In the fall of 2002, Jacob's doctors prescribed Zoloft initially, and when that did not help, they described Effexor. Jacob worsened and on October 10, 2002, he committed suicide in his parents' home. At that time, the FDA required the following precaution: "Suicide -- The

possibility of a suicide attempt is inherent in depressive disorder and may persist until significant remission occurs. Close supervision of high risk patients should accompany initial drug therapy. Prescriptions . . . should be written for the smallest quantity of tablets consistent with good patient management, in order to reduce the risk of overdose." (Filing No. 49, Appendix at 275-76.)[1] Plaintiffs contend that Nebraska common law requires a finding that the warnings given by the defendants about the risk of suicide were inadequate.

Discussion

The only issue before the court is whether the federal law preempts the Nebraska state law in this regard. State law which conflicts with federal law is preempted under the Supremacy Clause of the United States Constitution. U.S. Const., Art. VI, cl. 2. The FDA monitors the safety of drugs for consumers, and the FDA requires certain warnings on drugs. The FDA regulates advertising, warnings, labeling, misbranding, approval, and withdrawal of approval. Such warnings can be changed after approval by the FDA if research so dictates. A manufacturer can make changes and later ask for FDA approval. 21 C.F.R. § 314.70(c)(6)(iii)(A).

Preemption may occur when (1) Congress expressly preempts state regulation; (2) Congress intends federal law to "occupy the field"; or (3) state law conflicts with federal law. *Crosby v. National Foreign Trade Council,* 530 U.S. 363, 372 (2000). The Eighth Circuit has recently stated:

> A state law may be either expressly or impliedly preempted by federal law. Express preemption exists when a federal law explicitly prohibits state regulation in a particular field. Implied preemption arises when a federal law completely occupies the field of regulation so that by implication there is no

[1]The FDA has now changed its position and requires the black-box label to include a warning of the possibility of suicide in pediatric patients. The FDA made this change in 2004.

> room for state regulation and the coexistence of federal and state regulation is not possible. *See Chapman v. Lab One*, 390 F.3d 620, 624 (8th Cir.2004). Preemptive language in a statute is to be read narrowly, *Cipollone v. Liggett Group, Inc*., 505 U.S. 504, 518-19, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992), and without clear congressional intent there is a general presumption against finding implied preemption. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996); *Cliff v. Payco General American Credits, Inc*., 363 F.3d 1113, 1125 (11th Cir.2004); *Springston v. Consolidated Rail Corp*., 130 F.3d 241, 244 (6th Cir.1997). Implied preemption is therefore rarely found and only when the state law is in direct conflict with or frustrates the purposes of the federal law. *See, e.g., CTS Corp. v. Dynamics Corp. of Am.*, 481 U.S. 69, 78-79, 107 S.Ct. 1637, 95 L.Ed.2d 67 (1987).

Missouri Board of Examiners v. Hearing Help Express, Inc., 2006 WL 1277119 *2 (8th Cir. May 11, 2006). The Eighth Circuit has also held that "FDA regulations are generally minimal standards." *Hill v. Searle Labs*, 884 F.2d 1064, 1068 (8th Cir. 1989); *see also, Wells v. Ortho Pharm. Corp*., 788 F.2d 741, 746 (11th Cir. 1986) ("An FDA determination that a warning is not necessary may be sufficient for federal regulatory purposes but still not be sufficient for state tort law purposes.")

A. Conflict With State Law

There is no issue with regard to the first or second area of preemption outlined in *Crosby*. This court, then, is presented with an issue of whether there is a conflict between state and federal law. Defendants argue that Nebraska common law requires stronger warnings than the federal regulatory scheme. Defendants argue that the FDA has repeatedly reviewed research to determine if these types of drugs increase the risk of suicide and has determined that the language required on labels adequately addressed the potential risk. Ex. 5; Ex. 8 at 1. Defendants believe anything more would not have been supported by the evidence. *Id*. In addition, the FDA received evidence that if additional warnings were placed on the labels, patients might not take the antidepressant which might

actually increase the risk of suicide. Ex. 3, 9/20/91 PDAC Tr. at 27-28, 50-51, 89-92, 99-100, 103-06; Depo. of Dr. Paul Leber at 129.

In enacting amendments to the FDCA in 1962, Congress made it clear that state laws would still be valid, although conflicts between state and federal law would be preempted. Congress stated: "Nothing in the amendments made by this Act to the Federal Food, Drug and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments **unless there is a direct and positive conflict between such amendments** and such provisions of State law." Pub. L. No 87-781, 76 Stat. 780, 793 (1962) (emphasis added).

To date the Eighth Circuit Court of Appeals has not ruled on this exact issue. However, a number of district courts have very recently ruled that state court tort claims for failure to warn in drug cases are not pre-empted. *See Laisure-Radke v. Par Pharmaceutical, Inc., 2006 WL 901662 *4 (W.D. Wash. March 31, 2006) and 2006 WL 901657 * 2-6 (March 29, 2006) (*plaintiff could bring state law claim for failure to warn of increased risk of suicidality of antidepressant drug fluoxetine as state law not preempted*,* statement would not be false and misleading, and no frustration of Congressional purpose existed*); Peters v. Astrazeneca, LP,* 417 F. Supp. 2d 1051, 1055 (W.D. Wis. 2006) *(*no preemption over state law where FDA did not require a warning on the product); *McNellis v Pfizer*, 2005 WL 3752269 *10 (D.N.J. December 29, 2005) (common law failure to warn claim not preempted by federal law in Zoloft suicide case, and product not considered mislabeled because the label is strengthened, but burden on plaintiff to prove defendant's knowledge of suicide); *Zikis v. Pfizer, Inc*., No. 04C8104, 2005 WL 1126909 (N.D. Ill. May 9, 2005) (Ex. 5) (finding state court claims not preempted, and manufacturer can add additional warnings and that

manufacturer can comply with both FDA and state requirements); *Witczak v. Pfizer, Inc*., 377 F. Supp. 2d 726, 728-30 (D. Minn. 2005) (manufacturer can unilaterally strengthen a warning; requirement by FDA to use label verbatim did not preempt state law failure to warn claim; and prohibition against false and misleading labels did not preempt failure to warn claims); *Cartwright v. Pfizer, Inc*., 369 F. Supp. 2d 876, 881- (E.D. Tex. 2005) (FDA warning label requirement is a minimum standard of conduct); *but see*, *Dusek v. Pfizer Inc*., No. H-02-3559, 2004 WL 2191804 (S.D. Tex. Feb. 20, 2004) (finding preemption by FDA of state law warning requirements), and *Needleman v. Pfizer Inc.*, No. 3:03CV3074N, 2004 WL 1773697 (N.D. Tex. Aug. 6, 2004) (Ex. 4) (same). As stated by Chief Judge James Rosenbaum in *Wictzak*:

> Defendant's preemption argument has a surface appeal: Should it face state law liability for a failure to warn even though its label fully complied with federal law? But the argument fails upon scrutiny. Federal labeling laws are minimum standards; they do not necessarily shield manufacturers from state law liability. The primary purpose of both the FDCA and the FDA's regulatory scheme is to protect the public. State-law protections reinforce and enhance this objective. Defendant's preemption argument ultimately fails because Congress has not expressed a specific intent to preempt state consumer-protection laws in the area of prescription-drug labeling. In the absence of Congress's express statement, defendant must overcome the presumption against implying Congressional preemptive intent. It has not done so. As a result, plaintiff's state law claims remain viable.

Witczak, 377 F. Supp.2d at 732.

The court must now determine if there exists a conflict between Nebraska state law and federal law. A product is defective under Nebraska law if the instructions or warnings are inadequate. *Freeman v. Hoffman-LaRoche, Inc*., 618 N.W.2d 827, 841 (Neb. 2000). Nebraska law contemplates that some drugs will be dangerous, but contemplates that the seller will give proper warning. *Id*. at 835, *citing*, *Restatement (Second) of Torts § 402*,

Comment k. In addition, a prescription drug is not safe if the warnings are not provided to health care providers or in some cases the patient. *Freeman*, 618 N.W.2d at 571; Restatement (Third) of Torts (Products Liability) § 6(d).

Defendants contend that to apply a state standard in this case would substantially interfere with the specific federal requirements. Defendants argue that if plaintiffs' argument is adopted, defendants would have been required to violate FDA policy. The FDA required that the antidepressants use the exact language specified by it with regard to suicide. Defendants argue that the FDA looked at the suicide issue in the 1990's, 2002, and 2003 and determined the industry lacked sufficient evidence to require a warning of suicide. According to defendants, after conducting and reviewing years of test results, the FDA did not believe that sufficient evidence existed to note an increased risk of suicide.[2]

The court finds the analysis of the *Laisure-Radke, Peters, Hill* and *Witczak* to be persuasive. There has been no Congressional directive that the field is preempted. The recent notice issued by the FDA claiming preemption is not persuasive.[3] Further, the Eighth Circuit has adopted the minimum standards analysis when reviewing FDA regulations and has recently stated in *Missouri Bd. of Examiners* that implied preemption is rarely found, absent a direct conflict or a frustration of federal purpose. In addition, there has been no

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[2]Defendants rely on *Brooks v. Howmedica, Inc.,* 273 F.3d 785, 795 (8th Cir. 2001) (plaintiff in a Medical Devices Act case filed failure to warn claim which court found to be preempted) . The court notes that *Brooks* dealt with a medical device bone cement and did not deal with prescription drugs.

[3]*See* 21 C.F.R. parts 201, 314, 601; 71 Fed. Reg. 3,922, 3,934, 3,969, and 3,935-36 (January 24, 2006) ((January 24, 2006, statement by FDA that it intends to preempt the field with regard to labeling). The FDA failed to comply with its requirements to communicate with the states and to allow the states an opportunity to participate in the proceedings prior to a preemption decision. Executive Order 13132, Section 4 (c) (regulatory preemption must be kept to a minimum level), 4(d) (agency shall consult to extent practicable with the state and local officials to avoid the conflict) , 4(e) (if agency acts through adjudication or rulemaking to preempt the law of the state, it shall provide state and local officials with notice and an opportunity to participate).

showing that the Nebraska failure to warn law in any way directly conflicts with the FDA label requirement nor is there a showing of frustration of purpose as set forth in *Missouri Bd. of Examiners*. Further, the regulations clearly permit unilateral strengthening of the labeling. 21 C.F.R. § 314.70(b). Finally, the Fourth Circuit has stated that compliance with federal regulations will not absolve a manufacturer from liability. *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975). Based on the foregoing, the court finds that federal law does not preempt state law on the issue of failure to warn.

B. Misbranding

Defendants also contend that such a requirement about suicide could easily violate the statutory prohibition against misbranding. "The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." 21 C.F.R. § 201.57(e). Absent such evidence of association, and none existed in 2002 argues defendants, requiring a suicidal label would have violated the misbranding provision.[4] Defendant Wyeth argues that twice - once in September 2002 and again in August 2003 - it attempted to include pediatric, suicide-related warnings. On both occasions, Wyeth contends, the FDA did not insert those warnings. The *Needleman* and *Dusek* opinions, argue defendants, are directly on point. *See also Ehlis v. Shire Richwood, Inc*., 233 F. Supp. 2d 1189, 1198 (D.N.D. 2002), *aff'd on other grounds*, 367 F.3d 1013 (8th Cir. 2004) (granting summary judgment at trial court level

[4]The court notes that the defendants contend that the government filed amicus briefs in the cases of *Kallas v. Pfizer, Inc*., Case No. 2:04CV0998 (D. Utah filed September 29, 2005) and in *Colacicco v. Apotex, Inc.*, 05CV05500 (E.D. Pa. May 10, 2006) wherein the government argued that the additional state law warning label would have been "false and misleading" under federal law and that the FDA has preempted state tort law failure to warn claims. This court will not treat amicus briefs as the force of law. *See McNellis v. Pfizer*, 2005 WL 3752269 at 10 (D.N.J. December 29, 2005).

on ground that FDA approval of warning regarding specific alleged side effect preempted any different warning).

Plaintiffs argue that strengthening the label would not have made the label false and misleading. The court in *Witczak* noted that the FDA regulations permit a manufacturer to strengthen its warnings any time without the approval of the FDA, relying on 21 C.F.R. § 314.70(c)(6)(iii)(A) (permits the company to add or strengthen a warning). *Witczak* at 729. The court further found that it was not "impossible for [Pfizer] to comply with both state and federal requirements." *Id*. With regard to the defense that a label different from the one dictated by the FDA would be "false and misleading," the *Witczak* court found that the misbranding statute set forth in 21 U.S.C. § 355(e) did not make it impossible for the manufacturer to comply with a state failure to warn law. *Id*. at 730. Further, the court held that state consumer protection laws complemented rather than frustrated the FDA's job. *Id*. at 732. This court agrees and finds defendants' claims in this regard to be without merit.

THEREFORE, IT IS ORDERED that defendants' motions for summary judgment, Filing Nos. 39, 46, and request for hearing, Filing No. 71, are denied.

DATED this 31st day of May, 2006.

BY THE COURT:

s/Joseph F. Bataillon
JOSEPH F. BATAILLON
United States District Judge